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01 February 2016

Version of attached file:

Published Version

Peer-review status of attached file:

Peer-reviewed

Citation for published item:

Rajasekhar, P. and Rees, C. and Rutter, M. and Hungin, P. (2014) 'Developing a clinical research network : the Northern Region Endoscopy Group experience.', *Clinical medicine*, 14 (2). pp. 107-112.

Further information on publisher's website:

<http://dx.doi.org/10.7861/clinmedicine.14-2-107>

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Developing a clinical research network: The Northern Region Endoscopy Group experience

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ABSTRACT

Research is central to the National Health Service. Clinical trial recruitment has been aided by the National Institute for Health Research's Comprehensive Research Network but these networks do not support development of research. The Northern Region Endoscopy Group (NREG) was founded in 2007, encompasses 17 endoscopy units and has become a highly successful collaborative research network. The network is now a major contributor to UK trials, has published over 20 papers (>60 abstracts) and holds grants totalling more than £1.5 million. The NREG provides an exemplar model of how collaborative working can contribute significantly to biomedical research.

KEYWORDS: Network, research, collaboration, quality, National Institute for Health Research, NIHR, Northern Region Endoscopy Group

Background

The NHS is one of the largest organisations in the world and provides an ever-increasing range of services to its users. Maintaining and continually improving the quality and efficiency of services provided within the NHS through research, audit and service improvement is crucial.¹ There is often clinician enthusiasm but becoming involved in research

can be daunting. The complexities of research along with the pressure of clinical workload can be a barrier. Many see research as the preserve of large institutions with strong academic backgrounds. In addition, many clinicians working in smaller units may have insufficient patient numbers or support to undertake meaningful research. The National Institute for Health Research (NIHR) Comprehensive Clinical Research Network (CCRN) has helped to increase research activity; however, the development of research studies falls outside its remit. Development of collaborative networks at a clinical level is essential to drive research forward within the NHS.

This paper describes the model of the Northern Region Endoscopy Group (NREG), a highly successful clinical research network in the north of England. Since its inception in 2007, the NREG has established itself as one of the leaders in endoscopy research in the country, with a growing reputation internationally. The authors describe how this has been achieved and how this model could be replicated in other specialties and regions to complement the role of existing NHS research organisations.

Why develop a clinical research network?

The NHS offers a unique environment in which to conduct research and has the potential to deliver outstanding work. Few countries can deliver the relative uniformity of care and standards provided by the NHS. The NHS should lead world biomedical research. Historically, the majority of NHS research has taken place in larger academic hospitals with very little led from smaller units. It may not be possible to generalise single centre or academic centre research because these units might not be representative of wider clinical care. Furthermore, as most patients are managed in district general hospitals, there are likely to be fewer opportunities to become involved in research.

The establishment of the NIHR in 2006, and subsequently the CCRN and comprehensive local research networks (CRLNs), has stimulated greater involvement in research in England. This has been achieved through the provision of support costs to NIHR-approved clinical research studies that are included in the NIHR CRN portfolio and through assistance in the local approvals process.^{2,3} Clinicians with research ideas, however, still face the challenge of obtaining funding, developing research protocols and gaining the appropriate approvals before commencing studies. In addition, non-NIHR-funded research projects, as well as audit, service improvement

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work and development of regional databases, all of which are important, are not within the remit of these organisations. Clinical research networks help bridge such gaps by providing complementary support to the NIHR in areas where it cannot currently offer assistance.⁴

Conducting research within a network allows large-scale, well-coordinated research studies to be performed, in contrast to multiple small studies that may not be reproducible. Networks also provide the opportunity for units of varied sizes to become involved in research, which consequently means that the results produced will be more generally applicable. Finally, clinical research networks allow research and other projects to be led from smaller units while providing the support and resources of larger centres, together with patient populations, thus developing and encouraging a research culture throughout the NHS.⁴

How to develop a clinical research network

The Northern Region Endoscopy Group was formed in 2007 (joined by Leeds in 2012) with the aim of delivering a high-quality, region-wide research, service improvement and audit projects. The area covered is shown in Fig 1. Regular meetings are open to all with an interest in and enthusiasm for endoscopic research. The group has a representative from each organisation within the region, with each unit's link person acting as a representative for that unit, in addition to being able to disseminate the information back to their colleagues. Regardless of size, all units are accorded equal status. During meetings, new research ideas are proposed and developed, and updates given on projects that are under way. New projects are brought forward by an enthusiast who subsequently leads the study. Each project also has an individual steering group supported by the NREG committee.⁵

The NREG is an unofficial clinical research network from the perspective of the NIHR, although both the chair and the

vice-chair are specialty group leads for their respective CLRNs. The group has terms of reference and is accountable to the committee, which has representation from each member trust.

Initial resources included the time, enthusiasm and energy of the NREG's founding members. Financial support was from industry, the strategic health authority (SHA) and the chair's trust (South Tyneside Foundation Trust), who recognised the potential and early success of the NREG. This support was initially small and grew with the success of the group.

NREG had two early aims:

1 Clinically important region-wide audit projects and retrospective service evaluation work

The benefit of this approach was demonstrating collaborative work, overcoming barriers together and producing rapid results in order to demonstrate the value to the service, encourage clinical engagement and establish a presence. This also led to publication of abstracts and full papers, thereby developing further enthusiasm and engagement. Educational events with high-profile speakers further enhanced the reputation of the network.

2 Involvement in larger studies to increase experience of research and develop resources for further work

The NREG prioritised involvement and recruitment to established NIHR studies, encouraging region-wide engagement through promotion at NREG meetings. This also highlighted the potentially complex nature of prospective research studies and, therefore, the importance of collaboration with academic organisations and key opinion leaders with a track record of producing high-quality research. The NREG has developed a strong partnership with Durham University, along with close collaboration with other academic institutions (Imperial College, Leeds University) and centres of excellence in the UK and abroad. The NREG has also developed strong links with industry including testing prototype technology and techniques.

After the achievement of these early aims, the NREG focused on forming an infrastructure that would allow high-quality collaborative research projects to be developed both within the region and through external collaboration.

Developing research ideas

Development of a research idea from infancy through to a proposal suitable for a grant application requires a long iterative process. This involves discussion of ideas and constructive feedback, ideally from individuals of varied backgrounds and experience to enable all perspectives to be explored. This process is difficult to achieve within smaller units both due to the time constraints of clinical commitments and because the required expertise may not be available. The NREG has been able to provide an environment, through collaboration of regional clinical expertise and local academic units, in which research ideas can progress to gain funding.

Research study support

Once funding has been secured the challenge of running a quality study begins. This initially consists of the development



Fig 1. Geographical area covered by the Northern Region Endoscopy Group.

of a study protocol and documents, gaining ethical and local research and development (R&D) approval, followed by recruitment, monitoring, data analysis and report writing. The NIHR and CCRN provide support with the approvals process and encourage recruitment through its remuneration mechanism; however, they do not provide support in identifying and overcoming barriers to recruitment. Collaboration with academic units, specifically Durham University's Clinical Trials Unit, has resulted in these processes being much smoother. Furthermore, local clinician collaboration allows region-wide study promotion and pooling of ideas on how improved recruitment can be achieved.

Barriers to success

Naturally there were some challenges during the initial period. These included delays in the local approvals processes, including difficulties with access for non-trust employees, and for audit and service improvement projects that are outside the remit of the NIHR. Solutions consisted of good communication with R&D leads from the NREG chair to expedite these processes. Funding was initially limited and compensated for by the enthusiasm of NREG's founding members. The NREG's progress led to interest from both the SHA and industry. A significant proportion of these initially limited resources was directed towards supporting recruitment to NIHR portfolio studies. Success in this area allowed funds to grow, facilitating further work. Engagement from member units was variable

initially; however, buy-in has increased with promotion and on demonstration of the success of the model. The complexity of the NIHR structure, particularly with regard to the funding processes, was also an initial barrier. This was overcome through collaboration with those with experience of these systems, including academic units and Durham University.

What can a clinical research network achieve?

The NREG is the first clinician-led research network of its kind in the UK and has provided an infrastructure in which enthusiastic individuals and units, regardless of size or reputation, present and develop ideas for research as well as encouraging involvement in established local and national studies.

Early audit and service improvement work benefited clinical areas by playing a crucial role in improving the quality and efficiency of the services evaluated, as well as increasing the profile of these areas. The results of one study have also contributed to upcoming changes in the recommended national standards for colonoscopy performance.⁶ The work has also led to publications that played an important part in creating local enthusiasm and enhancing the national and international reputation of NREG.

National gastrointestinal (GI) studies have benefited from NREG's promotion in its member units, leading to the two CRLNs covered by the NREG providing the highest number of recruits (by population size) to GI projects in the country (Fig 2). This increased research activity has also benefited

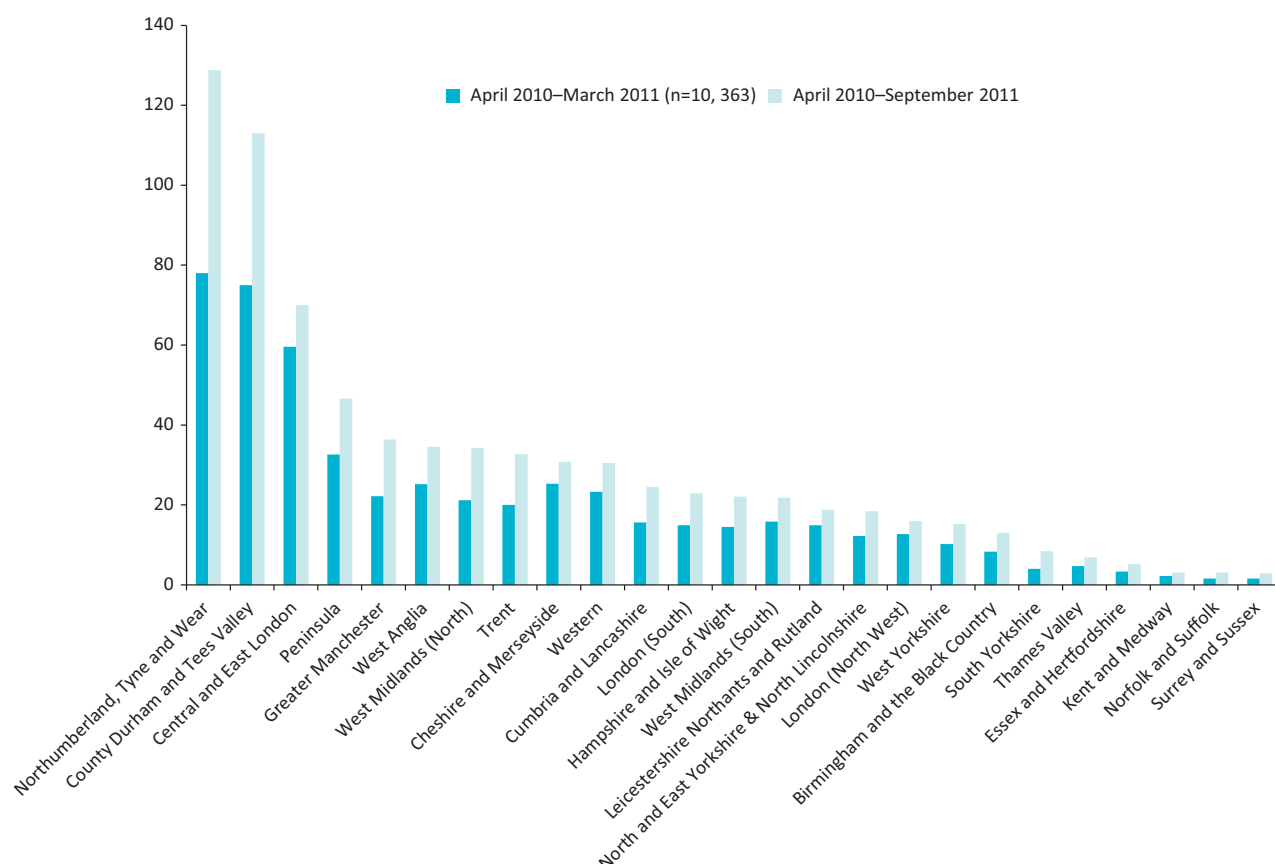


Fig 2. UK comprehensive local research network recruitment figures to gastrointestinal studies.

Table 1. Grants currently held or co-held by the Northern Region Endoscopy Group (NREG).

Study	Funding organisation	Amount secured	Grant holders
Barriers to Uptake of Colorectal Cancer Screening (2010)	NIHR RfPB	£45,000	CJ Rees, G Rubin, D Weller
SeAFOod (2010)	NIHR EME	£1.2 million	M Hull, CJ Rees, R Logan <i>et al</i>
Quality Improvement in Colonoscopy (2010)	SHA quality improvement grant	£52,000	CJ Rees, MD Rutter, JE East, BP Saunders
Biodegradable stent in benign oesophageal stricture compared to standard balloon dilatation treatment (BESST)	NIHR RfPB	£120,000	A Dhar, CJ Rees, D Dwarkanath, A Reddy, YKS Vishwanath, JRG Greenaway, JM Mason
Detect Inspect Characterise Resect and Discard (DISCARD) 2 trial (2011)	NIHR RfPB	£250,000	CJ Rees, A Ignatovic, H Close, JE East, BP Saunders, MD Rutter, J Mason
Barriers to Uptake of Flexible Sigmoidoscopy Screening	Policy Research Unit, DH	£120,000	G Rubin, CJ Rees, N Hall, D Weller, J Wardle
Qualitative analysis of engagement with Quality Improvement in Colonoscopy	Olympus Medical Grant	£10,000	CJ Rees, JE East, BP Saunders, MD Rutter
North East Interval Cancer study 2	Charitable funds	£20,000	CJ Rees, MD Gill, M Bradburn, S Mills, M Bramble, C Parker, TJW Lee, Y Bury, M Hull

DH = Department of Health; NIHR = National Institute for Health Research; NREG = Northern Region Endoscopy Group; RfPB = research for patient benefit; SeAFOod = Systematic Evaluation of Aspirin and Fish Oil; SHA = strategic health authority.

patients who now have a greater opportunity to become involved in research studies that may not have previously been available. Furthermore, resources, as well as enthusiasm, were generated for the development of subsequent work.

The collaborative partnerships forged as a result of the work of the NREG have allowed clinicians to share resources and knowledge, and move more rapidly along the learning curve associated with starting a career in research. Many clinicians with research enthusiasm, but no prior track records in research, have been engaged. Before the establishment of the NREG there were no academic endoscopy appointments and only a handful of consultants recruiting to clinical trials. There are now four NREG consultants appointed to senior academic posts; several now hold grants and are leading their own studies, and approximately 25 are involved in trials as local principal investigators. Furthermore, non-endoscopic research studies in gastroenterology and hepatology are also promoted at NREG meetings, providing a stimulus for recruitment in these areas.

The successful development of academic links has led to several successful grant applications for both collaborative and NREG-led studies totalling approximately £1.5 million. The grants secured are summarised in Table 1. This has greatly benefited trainees in gastroenterology within the region through the creation of several clinical and research fellow posts, thereby increasing opportunities to become involved in a wide range of studies including research, audit and service evaluation work. The NREG has delivered a wide range of studies and there are currently six funded endoscopy research fellows working in the region on projects involving the NREG where before there were none. The studies, those working on each study and the product of each study to date, are summarised in Table 2.

The NREG has also played a role in attracting the endoscopy industry back to the UK for the evaluation of technology and

research. This has led to investment in the NREG with several research fellows and nurses funded by industry.

All research, service improvement and audit work must be performed with the aim of delivering the best possible care to patients. The service improvement and audit work performed by the NREG within the region has meant that patients have access to a higher-quality, more efficient service. The work with primary care on barriers to uptake of bowel cancer screening has the potential to greatly improve understanding of why patients decline the invitation to participate and, therefore, to increase uptake by addressing these concerns. This has the potential to significantly influence mortality and morbidity from this common disease. Finally, as a result of the increase in research activity, the opportunity for patients to become involved in research studies is ever increasing, no matter where their care is based.

An important factor in evaluating the NREG's success is that most of it has been achieved with very little financial outlay. The resources on which the NREG was based were the valuable time, expertise and enthusiasm of its founding members, and this remains vital to its continued success. The subsequent resources generated through recruitment to NIHR studies and successful grant applications, achieved through collaborations as discussed below, have allowed the group to succeed and grow.

Collaboration

The key to the success of the NREG is inclusivity and collaboration. This was initially between local enthusiasts and, as the group developed, with regional, national and international academic units, clinical centres of excellence and key industry leaders. The growing reputation of the NREG is such that the group is frequently approached by national and international units wishing to collaborate on research studies (Table 2).

Table 2. Summary of Northern Region Endoscopy Group (NREG) research projects, trainees and selection of published work and presentations.

Study	Trainee	Selected publications and presentations
Evaluation of regional and national bowel cancer screening services	TJW Lee	Lee <i>et al</i> ⁷ Lee <i>et al</i> ⁸ Lee <i>et al</i> ⁹
Evaluation of regional and national bowel cancer screening services	D Majumdar	Majumdar <i>et al</i> ¹⁰ Majumdar <i>et al</i> ¹¹ Majumdar <i>et al</i> ¹²
A region-wide audit of ERCP	S Chatterjee	Chatterjee <i>et al</i> ¹³
Regional bowel cancer screening service evaluation	TJW Lee PT Rajasekhar	Lee <i>et al</i> ¹⁴ Rajasekhar <i>et al</i> ¹⁵ Rajasekhar <i>et al</i> ¹⁶ Lee <i>et al</i> ¹⁷
Quality Improvement in Colonoscopy (QIC) study	PT Rajasekhar	Rajasekhar <i>et al</i> ⁶ Rajasekhar <i>et al</i> ¹⁸ Rajasekhar <i>et al</i> ¹⁹
North East Interval Cancer study	MD Gill	Gill <i>et al</i> ²⁰ Gill <i>et al</i> ²¹ MD thesis (accepted), Durham University
Detect Inspect Characterise Resect and Discard (DISCARD) 2	PT Rajasekhar	Rajasekhar PT. <i>Discard II study – when can we leave polyps behind?</i> Presentation. World Endoscopy Organisation Colorectal Cancer Screening Committee Meeting, Orlando, USA.

ERCP = endoscopic retrograde cholangiopancreatography.

Conclusion

The NREG has demonstrated rapid growth and development over a 5-year period. Many clinicians with research enthusiasm but no prior track records in research have been engaged. This has allowed involvement in endoscopy research for many and a research career for some. The growing reputation of the group has led to collaboration with many co-investigators throughout the UK and internationally. The NREG was initially established with few resources other than enthusiasm and hard work with the subsequent success generating resources and allowing the development of higher quality research and the group to flourish. The success of the NREG has also led to many invitations to talk to both GI and other specialty groups on how the group was developed and success achieved. The model is now being followed in other areas of the UK. We would strongly encourage other clinical groups to replicate this model and develop similar clinical research networks. ■

Acknowledgements

We are grateful to all NREG members for their contribution towards its success. We also acknowledge Prof Mark Hull, Dr Roland Valori, Dr Andy Veitch and the British Society of Gastroenterology Endoscopy Research Group for their support and encouragement.

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